| MAY   | . 23.                         | 2006 3:50PM GW GLOBAL R&D IS  | NO. 1096P. 1                                    |  |  |  |  |  |  |  |  |  |  |
|---|-------------------------------|---|---|--|--|--|--|--|--|--|--|--|--|
| FORM P  | TO-1390                       | O (Modified) U.S. PATENT AND TRADEMARK OFFICE; U.S. DEPARTMENT OF COMMERCE  | ATTORNEY'S DOCKET NUMBER                        |  |  |  |  |  |  |  |  |  |  |
| TRANSMITTAL LETTER TO THE UNITED STATES  PB60384USW   |                               |   |   |  |  |  |  |  |  |  |  |  |  |
|   |                               | DESIGNATED/ELECTED OFFICE (DO/EO/US)  | U.S. APPLICATION NO. (If known, see 37 CFR 1.5) |  |  |  |  |  |  |  |  |  |  |
| C   |                               | CERNING A SUBMISSION UNDER 35 U.S.C. 371  | 10/564,180                                      |  |  |  |  |  |  |  |  |  |  |
|   |                               | ONAL APPLICATION NO. INTERNATIONAL FILING DATE  | PRIORITY DATE CLAIMED                           |  |  |  |  |  |  |  |  |  |  |
| PCT/EP2004/007668 July 8, 2004 July 11, 2003  |                               |   |   |  |  |  |  |  |  |  |  |  |  |
| TITLE OF INVENTION Pharmaceutical Formulations  |                               |   |   |  |  |  |  |  |  |  |  |  |  |
| Pharn   | The Historical A Ox Musiculus |   |   |  |  |  |  |  |  |  |  |  |  |
| A 0.01  | APPLICANT(S) FOR DO/EO/US     |   |   |  |  |  |  |  |  |  |  |  |  |
| Michael John MONTEITH, Anthony James TAYLOR, Marian THOMAS  |                               |   |   |  |  |  |  |  |  |  |  |  |  |
|   |                               |   |   |  |  |  |  |  |  |  |  |  |  |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following Items and other information: |                               |   |   |  |  |  |  |  |  |  |  |  |  |
| 1.  |                               |   |   |  |  |  |  |  |  |  |  |  |  |
| 2.  | _<br><b>X</b>                 | This is a SECOND or SUBSEQUENT submission of Items concerning a submission under 35 U.S.C. 371.   |   |  |  |  |  |  |  |  |  |  |  |
| 3.  |                               | This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below. |   |  |  |  |  |  |  |  |  |  |  |
| 4,  |                               | The US has been elected (Article 31).   |   |  |  |  |  |  |  |  |  |  |  |
| 5.  |                               | A copy of the International Application as filed (35 U.S.C. 371 (c)(2))   |   |  |  |  |  |  |  |  |  |  |  |
|   |                               | a.  is attached hereto (required only if not communicated by the International Bureau).   |   |  |  |  |  |  |  |  |  |  |  |
|   |                               | b. has been communicated by the International Bureau.   |   |  |  |  |  |  |  |  |  |  |  |
|   |                               | c. is not required, as the application was filed in the United States Receiving Office (RO/US).   |   |  |  |  |  |  |  |  |  |  |  |
| 6.  |                               | An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).  |   |  |  |  |  |  |  |  |  |  |  |
|   |                               | a. is attached hereto.  |   |  |  |  |  |  |  |  |  |  |  |
|   |                               | b. has been previously submitted under 35 U.S.C. 154(d)(4).   |   |  |  |  |  |  |  |  |  |  |  |
| 7.  |                               | Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))   |   |  |  |  |  |  |  |  |  |  |  |
| İ   |                               | a.   are attached hereto (required only if not communicated by the International Bureau).   |   |  |  |  |  |  |  |  |  |  |  |
| 1   |                               | b. have been communicated by the International Bureau.  |   |  |  |  |  |  |  |  |  |  |  |
|   |                               | c. D have not been made; however, the time limit for making such amendments has NOT expired.  |   |  |  |  |  |  |  |  |  |  |  |
|   |                               | d.  have not been made and will not be made.  |   |  |  |  |  |  |  |  |  |  |  |
| в.  |                               | An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).   |   |  |  |  |  |  |  |  |  |  |  |
| 9.  | $\boxtimes$                   | An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).   |   |  |  |  |  |  |  |  |  |  |  |
| 10.   |                               | An English language translation of the annexes to the International Preliminar Article 36 (35 U.S.C. 371 (c)(5)).   | y Examination Report under PCT                  |  |  |  |  |  |  |  |  |  |  |
| 11,   |                               | A copy of the International Preliminary Examination Report (PCT/IPEA/409).  |   |  |  |  |  |  |  |  |  |  |  |
| 12.   |                               | A copy of the International Search Report (PCT/ISA/210).  |   |  |  |  |  |  |  |  |  |  |  |
| It  | ems 1                         | 3 to 23 below concern document(s) or Information included:  | •   |  |  |  |  |  |  |  |  |  |  |
| 13.   |                               | An Information Disclosure Statement under 37 CFR 1.97 and 1.98.   | •   |  |  |  |  |  |  |  |  |  |  |
| 14.   |                               | An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.   |   |  |  |  |  |  |  |  |  |  |  |
| 15.   |                               | A FiRST preliminary amendment.  |   |  |  |  |  |  |  |  |  |  |  |
| 16.   |                               | A SECOND or SUBSEQUENT prellminary amendment.   |   |  |  |  |  |  |  |  |  |  |  |
| 17.   |                               | A substitute specification.   |   |  |  |  |  |  |  |  |  |  |  |
| 18.   | $\boxtimes$                   | A power of attorney and/or change of address letter.  |   |  |  |  |  |  |  |  |  |  |  |
| 19.   |                               | A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.  |   |  |  |  |  |  |  |  |  |  |  |
| 20.   |                               | A second copy of the published International Application under 35 U.S.C. 154(d)(4).   |   |  |  |  |  |  |  |  |  |  |  |
| 21.   |                               | A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4).   |   |  |  |  |  |  |  |  |  |  |  |
| 22.   |                               | Express Mail Label No.  |   |  |  |  |  |  |  |  |  |  |  |
| 1   |                               |   |   |  |  |  |  |  |  |  |  |  |  |

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U.S. APPLICATION NO //fikrosun\_cep 37 CEP 4.5

| U.S. APPLICATIO   | N NO (if known, see :   | 37 CFR 1.5)   | INTERNATIONAL     | INTERNATIONAL APPLICATION NO. |        |            | ATTORNEY'S DOCKET NUMBER |         |  |
|---|---|---------------|-------------------|-------------------------------|--------|------------|--------------------------|---------|--|
| <u> </u>  | 10/564,180  | PCT/EP200     | PCT/EP2004/007668 |                               |        | PB60384USW |                          |         |  |
| 23. Other item  | ns or information:  |               |                   |                               |        |            | ,                        |         |  |
| The following   | g fees have been s  | ubmitted:     |                   |                               |        |            | CALCULATIONS             | PTO USE |  |
|   |   |               | ,,,,,             |                               |        | \$300      | s <u>so.oo</u>           |         |  |
| If the written opin<br>prepared by IPEA   | ation fee (37 CFR<br>ion prepared by IS<br>VUS Indicates all c  | \$ \$0.00     |                   |                               |        |            |                          |         |  |
| 26. Search If the written opin by IPEA/US Search fee (37 C as an Inten International Sea previously | fee (37 CFR 1.492 ionof the ISA/US of Sindicates all clair FR 1.445(a)(2)) handlonal Searching rch Report prepare communicated to t | \$100         | \$ \$0.00         |                               |        |            |                          |         |  |
|   | L OF 24, 25 and   |               |                   | · · . · ·                     |        | 2200       | \$ \$0.00                |         |  |
| Additional fe sequence listing in an a The fee is \$2   | e for specification<br>sting in compliance<br>electronic medium<br>250 for each additi  |               |                   |                               |        |            |                          |         |  |
| Total Sheets  |   |               |                   |                               |        |            |                          |         |  |
| - 100 =   | 0 /50 =   |               | 0                 | 2                             | × \$25 | 0.00       | \$ \$0.00                |         |  |
| Surcharge of \$13 declaration after   | 0.00 for furnishing<br>the date of comme  | h or          | \$ \$130.00       |                               |        |            |                          |         |  |
| CLAIMS  | NUMBER F  | ILED          | NUMBER EXTRA      |                               | RATE   |            |                          |         |  |
| Total claims  |   | - 20 =        | 0                 | х                             | \$5    | 0.00       | \$ \$0.00                |         |  |
| Independent clair   | ms  | - 3=          | 0                 | х                             | \$20   | 0.00       | \$ \$0.00                | _       |  |
| MULTIPLE DEPE   | ENDENT CLAIMS   | (if applical  | ole)              | +                             | \$36   | 0.00       | \$ \$0.00                |         |  |
|   |   | NS =          | \$ \$130.00       |                               |        |            |                          |         |  |
| ☐ Applicant cla<br>1/2.   | alms small entity s   | by            | \$ \$0.00         |                               |        |            |                          |         |  |
|   |   | AL =          | S \$130.00        |                               |        |            |                          |         |  |
|   | f \$130.00 for furnis<br>ed priority date (37   | from          | \$ \$0.00         |                               |        |            |                          |         |  |
|   | F   | \$ \$130.00 · |                   |                               |        |            |                          |         |  |
| Fee for recording accompanied by  | the enclosed assi<br>an appropriate cov   | S \$0.00      |                   |                               |        |            |                          |         |  |
|   |   | \$ \$130.00   |                   |                               |        |            |                          |         |  |
|   | ·   |               | Amount to be      | s                             |        |            |                          |         |  |
|   |   |               |                   |                               |        |            | Amount to be             | \$      |  |
|   | -18   |               | <b>-</b> 1        |                               |        |            |                          |         |  |

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to cover the above fees is enclosed. a. A check in the amount of \$ In the amount of \$ \$130.00 to cover the above fees. 07-1392 b, 🔀 Please charge my Deposit Account No. A duplicate copy of this sheet is enclosed. c. 🔀 The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment 07-1392 A duplicate copy of this sheet is enclosed. to Deposit Account No. information should not be included on this form. Provide credit card information and authorization on PTO-2038. NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status. SEND ALL CORRESPONDENCE TO: 23347 J. Scott Young NAME 45,582 REGISTRATION NUMBER May 23, 2006 DATE